### Docket No.: 1752-0171PUS1

## REMARKS

Claims 24 and 30-35 are currently pending in the present application. Claims 1-23 and 25-29 have been canceled. Claim 24 has been amended herein. New claims 30-35 have been added. Support for the claim amendments may be found in the specification at page 2, the last line bridging to page 3, line 5; page 3, lines 5-13; page 13, line 23; page 18, lines 21-24 and page 20, lines 19-20. Applicants submit that no new matter has been added by way of the present amendment.

## Preliminary Matter

Applicants submitted an Information Disclosure Statement dated March 20, 2006. However, the Examiner has not indicated that the references have been considered. Applicants respectfully request that the Examiner consider the references cited on the IDS and provide a copy of the initialed and signed document.

#### Title of the Invention

The Examiner has objected to the title of the invention as not being descriptive. According to the Examiner's suggestion, Applicants have amended herein the title of the present invention to recite "Method For Promoting Immunotherapy."

# Issues Under 35 U.S.C. § 112, Second Paragraph

Claims 21, 24-27 and 29 have been rejected as being indefinite for failing to particularly point out and distinctly claim the present invention.

Claims 21, 26, 27 and 29 have been canceled herein, thus rendering the outstanding rejection moot.

With regard to claim 24, the Examiner finds the language "a functional derivative" vague and indefinite. Claim 24 has been amended to clarify what is meant by a functional derivative. In particular, claim 24 now recites,

"an agonist compound selected from the group consisting of MIP-1 $\alpha$ , BB-10010, and MIP-1 $\alpha$  which is chemically modified with partially alkyl-esterified styrene-maleic acid copolymer or polyethylene glycol derivative, and BB-10010 which is chemically modified with partially alkyl-esterified styrene-maleic acid copolymer or polyethylene glycol derivative"

Applicants respectfully submit that the claim amendment clarifies the metes and bounds of the present claim.

The Examiner further rejected claim 24 because the phrase "a dendritic cell precursor level" was considered vague and indefinite. Claim 24, as currently amended, does not recite a dendritic cell precursor level, and instead references a dendritic precursor cell. This phrase is used frequently throughout the specification, and is explained sufficiently at page 1, line 20-page 2, line 5 and page 6, lines 20-24. It is clear from these passages that dendritic precursor cells are immature dendritic cells constantly supplied in the steady state from the bone marrow into organs via blood circulation in the living body. These precursors represent stage (2) of the proliferation, differentiation and maturation process of dendritic cells. Moreover, they exist only in a small amount in the peripheral blood.

In view of the above remarks, Applicants respectfully request reconsideration and withdrawal of the outstanding rejection.

#### Issues Under 35 U.S.C. § 102

The Examiner has rejected claims 24 and 25 as being anticipated by Bernstein et al. (1997). Applicants respectfully traverse.

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Bernstein only discloses the biological and clinical effect of BB-10010 for patients receiving chemotherapy and concludes that BB-10010 has no effect on reducing the toxicity of such therapy (see page 888, Abstract). Bernstein neither discloses nor suggests that BB-10010 has an activity of "elevating concentration level of dendritic cell precursors in peripheral blood."

The novelty of the present invention lies in the fact that MIP-1 $\alpha$ , BB-10010 or the chemically modified derivatives thereof, elevates the concentration level of dendritic cell precursors in the peripheral blood. Bernstein does not recognize this novel feature. Moreover, in the present invention, BB-10010 is not used together with chemotherapy.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Since the Bernstein does not teach each and every element of the claimed invention, Applicants respectfully request withdrawal of the outstanding rejection.

#### Issues Under 35 U.S.C. § 103

The Examiner has rejected claims 26, 27 and 29 as being rendered obvious by Bernstein in view of Shadle et al. (USP 4,847,325). Applicants respectfully traverse.

In light of the present claim amendments, the outstanding rejection is moot. However, Applicants make the following remarks to the extent that Bernstein in view of Shadle may be applied against the present claims. Although Shadle et al. teach PEGylation of M-CSF and its effect in vivo, as pointed out by the Examiner, Shadle et al. do not suggest that chemically modified MIP- $1\alpha$  or BB-10010 have any effect of elevating concentration level of dendritic cell precursors in the peripheral blood. Thus, it is respectfully submitted that the combination of Bernstein et al. and Shadle et al. do not teach or suggest the present invention.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Monique T. Cole (Reg. No. 60,154) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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